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PREMARKET NOTIFICATION

510(k) SUMMARY

NOV 1 6 2009

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____ Date: 2008.08.27

1. Submitter:

Health & Life Co., Ltd.
9F, No.186, Jian Yi Road. Chung Ho City, Taipei County, Taiwan, R.O.C.
TEL : +886-2-8227-1300
FAX : +886-2-3234-9601

Contact person: Sarah Su/ Regulatory Affairs Dept.
E-mail: sarah.su@hlmt.com.tw
Tel: 886-2-8227-1300 ext.1201
Fax:886-2-3234-9601

2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL168KB
Common Name: Blood Pressure Monitor
Classification Name: Noninvasive Blood Pressure Measurement System
Classification: Class II, 21CFR 870.1130
Product Code: DXN
Panel: Cardiovascular

3. Information for the 510(k) Cleared Device (Predicate Device):

A. Full Automatic (NIBP) Blood Pressure Monitor, Model HL168FV, K060729
B. Digital Wrist Blood Pressure Monitor, Model HEM-609N, K042505
C. Wrist Blood Pressure monitor, Model WS-1100, K080177

4. Device Description:

HL168KB automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this

over-the-counter device is for over the age of 18 with wrist circumference ranging from 135 mm to 195 mm (Approx. 5.3~7.7 inches) and for home use.

The user is able to set the personal target value and the device will flash the value when the measured blood pressure value exceeds the target one. Also, user can save and manage the measurement data by transferring the measured readings of blood pressure to the connected personal computer (PC) via USB cable.

Additionally, the device will display a symbol of  or  , to indicate the detection of irregular heartbeat rhythm as defined as a rhythm is more than or less than 25% from the average heartbeat during the measurement.

5. Intended Use

HL168KB automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for over the age of 18 with wrist circumference ranging from 135 mm to 195 mm (Approx. 5.3~7.7 inches) and for home use.
When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings. And this device can let the storage data be transferred to the connected personal computer (PC) via USB cable.

6. Comparison of device to predicate device:

Product Specification Comparison Table of HL168KB and HL168FV (K060729)

Item	HL168KB	Predicate HL168FV (K060729)
Method of measurement	Oscillimetric	Oscillimetric
Range of measurement	Pressure 0- 300mmHg, Pulse 40-199 Beats/minute	Pressure 0- 280mmHg, Pulse 40-200 Beats/minute
Accuracy	Pressure +/− 3mmHg Pulse +/− 5%	Pressure +/− 3mmHg Pulse +/− 5%
Inflation	Automatic inflation (Air pump)	Automatic inflation (Air pump)
Deflation of Pressure	Automatic air release control valve	Automatic air release control valve
Exhaust	Automatic exhaust valve	Automatic exhaust valve
Display	Liquid Crystal Digital Display	Liquid Crystal Digital Display

Sets of memory	3*40 , total 120	3*40, total 120
Cuff size	Wrist circumference approx. 135 ~ 195 mm (Approx. 5.3~7.7 inches)	Wrist circumference approx. 135 ~ 195 mm
Operating Temperature	10℃ ~ 40℃ , (50°F~104°F), 15%~90%R.H.	10℃ ~ 40℃ , 30%~85%R.H.
Storage Temperature	- 20℃ ~ + 70℃, (- 4°F~ +158°F), ≦90%R.H.	- 20℃ ~ + 50℃, 10%~95%R.H.
Power Supply	2 × "AAA" (1.5V) Alkaline battery	2 × "AAA" (1.5V) Alkaline battery
Material	ABS housing and rubber keys	ABS housing and rubber keys
Number of Push Bottom	5	5
Storage pouch	Yes	Yes
Unit Weight	Approx. 148g including batteries	Approx. 104g including batteries
Screen Cover	None	Yes

Changes from the predicate devices HL168FV (K060729):

* 5 push buttons' positions, shapes, removing the cover of the screen

* Additional product features of Irregular Heartbeat Detector, Personal Target Limits, and PC Link functions

For the product features of irregular heartbeat detector, was compared with the other predicate device Omron HEM 609N (K042505).

For the product features of Personal Target Limits, was compared with the other predicate device Nissei WS-1100 (K080177).

7. Discussion of Clinical Tests Performed:

HL168KB is compliant to the ANSI/AAMI SP-10:2002+A1:2003+A2:2006 Standard for Manual, electronic, or automated sphygmomanometers. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

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8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. **Safety Test**: IEC 60601-1:1988+A1:1991+A2:1995 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

b. **EMC Test**: IEC 60601-1-2:2001+A1:2004 Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test

c. **Biocompatibility Test**: ISO 10993-1:2003 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing

d. **Biocompatibility Test**: ISO 10993-5:1999 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

e. **Biocompatibility Test:** ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

f. **Reliability Test**: ANSI/AAMI SP-10:2002+A1:2003+A2:2006

9. Conclusions:

The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 16 2009

Health & Life Co., Ltd.
c/o Mr. Tzu-Wei Li
Manager, Senior Administrator
Center for Measurement Standards Industrial Technology Research Institute
Rm. 30A, Bldg. 16, 321, Sec. 2 Kuang Fu Rd.
Hsinchu, Taiwan 30011
R.O.C.

Re: K092163
Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL168KB
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: October 29, 2009
Received: November 2, 2009

Dear Mr. Li

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092163

Indication for Use

510(k) Number (if known): _____

Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL168KB

Indications for Use:

HL168KB automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for over the age of 18 with wrist circumference ranging from 135 mm to 195 mm (Approx. 5.3~7.7 inches) and for home use.

When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings. And this device can let the storage data be transferred to the connected personal computer (PC) via USB cable.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __V___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092163